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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,934	01/02/2001	Julie R. Korenberg	2320-1-001PCT/US	8413

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,934	KORENBERG ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,15-17,19,20,23-31 and 58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,15-17,19,20,23-31 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The reply filed on 1/3/05 is acknowledged. Claims 1, 4, 17, 19, 20, 23, and 27-30 are amended. Claims 1-4, 15-17, 19, 20, 23-31, and 58 are pending and are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequence Rules, Withdrawn

The objection of the specification is withdrawn in view of the amendment to the specification.

Claim Objections, Withdrawn

The objection of claim 4 under 37 CFR 1.75(c) is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 101, Withdrawn

The rejection of claim 17 under 35 USC 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment.

The rejection of the claims 1-4, 15-17, 19, 20, 23-31, and 58 under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility is withdrawn because applicant's argument that the claimed invention is useful in diagnosing Down's syndrome is persuasive.

Claim Rejections - 35 USC § 112, Maintained

Claims 1, 3, 4, 15-17, 19, 20, 23-31, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This written description rejection is made the scope of the claims include genomic DNA encoding SEQ ID NO: 2.

Applicant argues that the rejection of the claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is moot because the claims are amended.

The amended claims are carefully reviewed in view of the comments in the reply. However, claims 1, 3, 4, 15-17, 19, 20, 23-31, and 58 remain rejected because the limitation "genomic DNA" in claim 4 (previously depended on claim 2 now depends on the base claim 1) indicates that the scope of claim 1 includes genomic DNA encoding SEQ ID NO: 2 protein. As stated before in the previous Office action mailed on 08/13/04 at page 12, 3rd paragraph, Guipponi et al., of record (01 November 1998, Genomics, vol. 53, pages 369-376) teach at page 370 that a genomic DNA includes "introns" among other DNA elements. The specification does not describe how the introns of the gene encoding SEQ ID NO: 2 look like. All of the rejected dependent claims are rejected because those claims also are drawn to genomic DNA.

Claims 1-4, 15-17, 19, 20, 23-31, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is □undue□ include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the claimed invention is interpreted as drawn to SEQ ID NO: 1 (a cDNA from SH3D1A gene) isolated from human chromosome 21 for use in detection of megakaryocytic abnormality (note the species election in response to the Restriction Requirement).

Applicant argues that the claimed invention is drawn to nucleic acids encoding SEQ IDS NO: 2. Further, the use of these sequences is not limited to detecting megakaryocytic abnormalities by measuring expression of SH3D1A.

These arguments have been fully considered but found unpersuasive because claim 58 is still drawn to the isolated nucleic acid of claim 1, wherein said nucleic acid is used for megakaryocytic abnormality.

As stated before in the previous Office action, the specification at page 53 lines 14-27 and Fig. 3 discloses that the SH3DIA is mapped to chromosome 21, and mRNA analysis obtained from an individual with familial platelet disorder (FPD) shows a significantly higher expression of SH3D1A.

However, one of skilled in the art would have a reason to doubt familial platelet disorder (FPD) or any other megakaryocytic abnormality could be detected by the claimed nucleic acids because the post-filing date publication, Song et al., (October 1999, Nature Genetics, vol. 23, pages 166-175) unequivocally teach at the abstract that that FPD is caused by mutations in CDFA2 gene, not SH3D1A.

Further, OMIM (Online Mendelian Inheritance in Men) with the update history of 2002 with the accession number #601399 downloaded on 7/28/04 from url>>ncbi.nlm.nih.gov also teaches that the art recognizes mutation in CDFA2 gene, not SH3D1A gene is associated with FPD megakaryocytic abnormality phenotype.

Considering the unpredictable state of art, limited guidance, no examples in the specification how to make nucleic acid capable of detecting megakaryocytic abnormality, and how to use the claimed invention, and broad breath of the claims, it is concluded that undue experimentation is required to practice the full scope of the invention.

Claim Rejections - 35 USC § 102

The rejection of the claims under 35 U.S.C. 102(b) as being anticipated by WO 96/31625 (10 Oct. 1996) is **withdrawn** because the amended claims are no longer anticipated by the art of record.

Claims 1, 3, 4, 17, 23-29, and 58 remain rejected under 35 U.S.C. 102(**b**) as being anticipated by Chen and Antonarakis (1997, Cytogenetics and Cell Genetics, vol. 78, pages 213-215).

Claims 1, 3, 4, 17, 23-29, and 58 are interpreted as drawn to isolated genomic DNA of the entire SH3DA1 gene encoding SEQ ID NO: 2, and said DNA in YAC clone (note the claim limitations in claim 4 and claim 26).

Applicant argues that Chen and Antonarakis (1997) use an exon (hmc02a08) mapping to chromosome 21 to probe cosimids and YACs. The exon encodes a partial sequence of SEQ ID NO: 2. Chen and Antonarakis (1997) do not teach the amino acid and nucleotide sequences set forth in the present application.

These arguments have been fully considered but found unpersuasive. As stated before in the previous Office action, Chen and Antonarakis especially at Fig. 1 teach two YAC clones of 838C7 and 860G11 between markers of D21S319 and D21S65, and the isolated genomic DNA from these two YAC clones, and several other cosmids all appear to contain the entire SH3D1A gene located between markers of D21S319 and D21S65 of human chromosome 21q22.1 to q22.2.

Although the reference does not specifically teach that the nucleic acid encodes SEQ ID NO: 2, the protein encoding DNA sequences are highly conserved, and those YAC and cosmids being amplified in the PCR using SH3D1A specific primers as shown in Fig. 1 all appear to contain the genomic DNA encoding the instant SEQ ID NO: 2. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the nucleic acids, especially those nucleic acids

contained in the YAC clones 838C7 and 860G11 of the prior art do not possess the same structural characteristics of the instantly claimed invention. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed invention is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

As for the probe use to diagnose megakaryocytic abnormality in instant claim 58, it is merely suggestive of an intended use and is not given patentable weight for purposes of comparing the claim with the prior art. The claim read on the nucleic acid *per se.*

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Judy Ladringan for Art Unit 1642 whose telephone number is 571-272-0536.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
4/11/03